MAY 1 4 2014

510(k) Summary
(Per 21 CFR 807.92)

General Company Information:

Nextremity Solutions, Inc.
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Date Prepared

February 20, 2014

General Device Information

Product Name:

MSP™ Metatarsal Shortening System

Classification:

Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3030
Product code: HRS

Smooth or Threaded metallic bone fixation fastener and accessories
21 CFR 888.3040
Product code: HWC
Class II device

Predicate Devices

Synthes, Inc.

Modular Mini Fragment LCP System
(Marketed as Modular Mini Fragment LCP System)
[510(k) K063049]

Description

The Nextremity Solutions MSP™ Metatarsal Shortening System is a set, consisting of:

1. A bone plate.
2. Specific length, cortical and locking screws.
3. Necessary surgical site preparation and insertion instruments (as a procedure pack).

The cortical and locking screw(s) are used in conjunction with the bone plate and are individually packaged.

The plate and screws are fabricated from medical grade Titanium and the design allows for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments found in the foot, particularly in osteopenic bone.

Intended Use (Indications)

The Nextremity Solutions MSP™ System is indicated for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments, particularly in osteopenic bone. Examples include, but not limited to, the hand, foot (shortening of the lesser metatarsal) and ankle.

Substantial Equivalence

The Nextremity Solutions, MSP™ Metatarsal Shortening System possesses the same technological characteristics of the predicate devices. These characteristics include the intended use, basic design, material, size and fundamental technology.

Performance Data

Mechanical testing was performed as described in relevant recognized standards, including 4 point bending (static and dynamic) for the MSP plate per ASTM F-382 and torque to failure for the screws per ASTM F-543. An axial push-out test was implemented to properly compare the predicate device to the proposed MSP screw designs given the short length of the screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

Nextremity Solutions, Incorporated
Mr. Jorge A. Montoya
Director, Product Development
54 Broad Street, Suite 200
Red Bank, New Jersey 07701

Re: K140724
Trade/Device Name: MSP™ Metatarsal Shortening System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 27, 2014
Received: March 28, 2014

Dear Mr. Montoya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140724

Device Name: MSP™ Metatarsal Shortening System

Indications For Use:

The Nextremity Solutions MSP™ System is indicated for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments, particularly in osteopenic bone. Examples include, but not limited to, the hand, foot (shortening of the lesser metatarsal) and ankle.

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices